

§ 868.1

21 CFR Ch. I (4–1–02 Edition)

868.2775 Electrical peripheral nerve stimulator.
868.2875 Differential pressure transducer.
868.2885 Gas flow transducer.
868.2900 Gas pressure transducer.

Subparts D–E [Reserved]

Subpart F—Therapeutic Devices

868.5090 Emergency airway needle.
868.5100 Nasopharyngeal airway.
868.5110 Oropharyngeal airway.
868.5115 Device to relieve acute upper airway obstruction.
868.5120 Anesthesia conduction catheter.
868.5130 Anesthesia conduction filter.
868.5140 Anesthesia conduction kit.
868.5150 Anesthesia conduction needle.
868.5160 Gas machine for anesthesia or analgesia.
868.5165 Nitric oxide administration apparatus.
868.5170 Laryngotracheal topical anesthesia applicator.
868.5180 Rocking bed.
868.5220 Blow bottle.
868.5240 Anesthesia breathing circuit.
868.5250 Breathing circuit circulator.
868.5260 Breathing circuit bacterial filter.
868.5270 Breathing system heater.
868.5280 Breathing tube support.
868.5300 Carbon dioxide absorbent.
868.5310 Carbon dioxide absorber.
868.5320 Reservoir bag.
868.5330 Breathing gas mixer.
868.5340 Nasal oxygen cannula.
868.5350 Nasal oxygen catheter.
868.5365 Posture chair for cardiac or pulmonary treatment.
868.5375 Heat and moisture condenser (artificial nose).
868.5400 Electroanesthesia apparatus.
868.5420 Ether hook.
868.5430 Gas-scavenging apparatus.
868.5440 Portable oxygen generator.
868.5450 Respiratory gas humidifier.
868.5460 Therapeutic humidifier for home use.
868.5470 Hyperbaric chamber.
868.5530 Flexible laryngoscope.
868.5540 Rigid laryngoscope.
868.5550 Anesthetic gas mask.
868.5560 Gas mask head strap.
868.5570 Nonrebreathing mask.
868.5580 Oxygen mask.
868.5590 Scavenging mask.
868.5600 Venturi mask.
868.5610 Membrane lung for long-term pulmonary support.
868.5620 Breathing mouthpiece.
868.5630 Nebulizer.
868.5640 Medicinal nonventilatory nebulizer (atomizer).
868.5650 Esophageal obturator.
868.5655 Portable liquid oxygen unit.
868.5665 Powered percussor.

868.5675 Rebreathing device.
868.5690 Incentive spirometer.
868.5700 Nonpowered oxygen tent.
868.5710 Electrically powered oxygen tent.
868.5720 Bronchial tube.
868.5730 Tracheal tube.
868.5740 Tracheal/bronchial differential ventilation tube.
868.5750 Inflatable tracheal tube cuff.
868.5760 Cuff spreader.
868.5770 Tracheal tube fixation device.
868.5780 Tube introduction forceps.
868.5790 Tracheal tube stylet.
868.5795 Tracheal tube cleaning brush.
868.5800 Tracheostomy tube and tube cuff.
868.5810 Airway connector.
868.5820 Dental protector.
868.5830 Autotransfusion apparatus.
868.5860 Pressure tubing and accessories.
868.5870 Nonrebreathing valve.
868.5880 Anesthetic vaporizer.
868.5895 Continuous ventilator.
868.5905 Noncontinuous ventilator (IPPB).
868.5915 Manual emergency ventilator.
868.5925 Powered emergency ventilator.
868.5935 External negative pressure ventilator.
868.5955 Intermittent mandatory ventilation attachment.
868.5965 Positive end expiratory pressure breathing attachment.
868.5975 Ventilator tubing.
868.5995 Tee drain (water trap).

Subpart G—Miscellaneous

868.6100 Anesthetic cabinet, table, or tray.
868.6175 Cardiopulmonary emergency cart.
868.6225 Nose clip.
868.6250 Portable air compressor.
868.6400 Calibration gas.
868.6700 Anesthesia stool.
868.6810 Tracheobronchial suction catheter.
868.6820 Patient position support.
868.6885 Medical gas yoke assembly.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 47 FR 31142, July 16, 1982, unless otherwise noted.

Subpart A—General Provisions

§ 868.1 Scope.

(a) This part sets forth the classification of anesthesiology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a pre-market notification submission for a device under part 807 may not show

merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, an anesthesiology device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[52 FR 17734, May 11, 1987]

§ 868.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA

or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

[52 FR 17734, May 11, 1987]

§ 868.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when: